B6 Contd

22. A method according to Claim 21 wherein the skin disease or condition is, has been or will be further treated by application of a corticosteroid.

Please add new Claim 30:

B7 Rule 126

31~~30~~. A method as in Claim 15 wherein said alkoxylated cetyl alcohol is polypropoxylated cetyl alcohol.

Remarks

Claims 1, 4, 13, 15, 17, 21, and 22 have been amended. Claims 20 and 29 have been cancelled. Claim 30 has been added. Claim 1, 3-5, 9-13, 15, 17, 21-23, 28, and 30 are now in the application. Consideration and allowance of these claims as now presented is respectfully requested.

Claim 4 has been amended to recite a particular alkoxylated cetyl alcohol in the form of PPG-5 Ceteth-20, which is the standard INCI nomenclature for an alkoxylated cetyl alcohol containing approximately five moles of propylene oxide and twenty moles of ethylene oxide. This well known INCI nomenclature is demonstrated in the attached Croda Raw Materials guide.

Rejection of Claims Under 35 U.S.C. §112

Claims 15, 17, 20, 21 and 22 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. The claims have been amended as suggested by the Examiner, and,

as such, the claim rejections thereon should accordingly be withdrawn.

Claims 13, 17, 20-21, and 29 stand rejected under 35 U.S.C. §112, second paragraph, for failing to distinctly claim the subject matter of the invention. Claim 13 has been amended as suggested by the Examiner to recite the commonly known transitional phase of "consisting essentially of".

With regard to the terms objected to in Claim 13 as being indefinite, page 1382 of Martindale, The Complete Drug Reference, 32nd Edition, specifically defines "light liquid paraffin" and "white soft paraffin" as distinct known materials. A copy of such definitions is attached herewith. Applicant therefore submits that such terms as used in claim 13 are well known to those of ordinary skill in the art.

Claims 17 and 21 have been amended as suggested by the Examiner to more distinctly claim the invention. As a result, the rejection of Claims 13, 17, 20-21, and 29 under 35 U.S.C. §112, second paragraph, should accordingly be withdrawn.

Rejection of Claims Under 35 U.S.C. §103

Claims 1, 3-5, 10-12, 15, 17, 20-21, 23, and 28-29 stand rejected under 35 U.S.C. §103(a) as being

unpatentable over Totten et al. (U.S. GB 2202145) in view of Motoaki et al. (EP 0189861), and further in view of Maurin (U.S. 5,888,478). Totten et al. '145 generally disclose dermatological compositions having nedocromil sodium and CREMOPHOR A6/CREMOPHOR A 25. Such CREMOPHOR compounds relate respectively to Ceteareth-6 and Ceteareth-25, which are ethoxylated mixtures of cetyl and stearyl alcohols. The presently claimed polypropoxylated cetyl alcohol has preferred properties distinct from those of polyethoxylated cetyl, lauryl or stearyl alcohol. In particular, polypropoxylated cetyl alcohol has unique and preferred humectant properties on skin, along with low skin sensitivity and good emollient properties. Nowhere in the cited art is the use of polypropoxylated cetyl alcohol disclosed for its advantageous properties in the composition of the present invention.

The primary essence of the present invention is the combination of an alkoxylated cetyl alcohol and an amphoteric surfactant in a pharmaceutical composition having a polar drug to provide an unexpectedly enhanced dermatological transmission of the polar drug. Neither Totten et al. '145, Motoaki et al. '861, nor Maurin '478, whether taken alone or in combination, teach or suggest the presently claimed compositions. The unexpected nature of

the presently claimed combination is demonstrated by the long-felt need in the art for the development of an acceptable vehicle that allows adequate skin penetration of a polar drug, and particularly sodium cromoglycate and nedocromil sodium (see page 3, line 28-page 4, line 3 of the present application). Had the combination of an alkoxylated cetyl alcohol with an amphoteric surfactant, as asserted by the Examiner, been obvious to those skilled in the art, compositions incorporating such a combination would have previously been developed due to the substantial need in the medical field therefor.

The documents cited by the Applicant detail the ineffectiveness of topical sodium cromoglycate treatments utilizing compositions previously known (see Haider, Treatment of Atopic Excema in Children, a Clinical Trial of Ten-Percent Sodium Cromoglycate Ointment, BMJ 1977, pages 1570-1572). Other attempts to provide a suitable transmission vehicle for the polar drugs failed due to the unstable nature of the compositions. Therefore, the combination of the present invention unexpectedly overcame such drawbacks by providing a stable composition which is effective in transdermally delivering a polar drug such as sodium cromoglycate or nedocromil sodium. Discussion of such unexpected results is found at page 5, lines 4-21, and

at page 30, line 10 to page 31, line 12 of the present application.

In addition, the unexpected benefits of the presently claimed compositions are set forth in the Declaration of Brian Hawtin enclosed herewith. The Declaration illustrates the instability and ineffectiveness of the compositions disclosed in the cited prior art. The presently claimed combination of an alkoxylated cetyl alcohol with an amphoteric surfactant therefore provides unexpected benefits in the transdermal transmission of a polar drug through topical treatment thereof. As such, the claim rejections under 35 U.S.C. §103(a) should accordingly be withdrawn.

Claims 1, 9, 15, and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Motoaki et al. '861, and further in view of Lezdey et al. (U.S. 5,190,917). Lezdey et al. '917 fail to cure the defects of Totten et al. '145 and Motoaki et al. '861 as discussed above. Therefore, the claim rejections based thereon should accordingly be withdrawn.

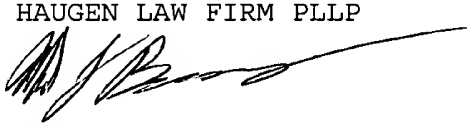
Claim 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145, Motoaki et al. '861, Timmons et al. (U.S. 4,883,792), and Collin et al. (U.S. 5,959,137). Timmons et al. '792 and Collin et al.

'137, whether taken alone or in combination, fail to cure the defects of Totten et al. '145 and Motoaki et al. '861. Thus, the claim rejections based thereon should accordingly be withdrawn.

For the foregoing reasons, the claims as presently amended are believed to be unobvious and patentable over the cited prior art, whether taken alone or in combination. Applicants therefore submit that the claims as currently presented are allowable on the merits. An early allowance is respectfully solicited.

Respectfully submitted,

HAUGEN LAW FIRM PLLP



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Attachments

Version with Marking to Show Changes Made

In the Claims

Please cancel Claims 20 and 29.

Please amend Claims 1, 4, 13, 15, 17, 21, and 22 as follows.

1. A composition comprising an amphoteric surfactant, [an alkoxylated] a polypropoxylated cetyl alcohol and a polar drug selected from the group consisting of sodium cromoglycate and nedocromil sodium, said composition further comprising an aqueous phase and an oil phase.

4. A composition according to Claim 1, including ethoxylated cetyl alcohol, said polypropoxylated and ethoxylated cetyl alcohols being included in said composition in the form of PPG-5 Ceteth-20 [wherein the alkoxylated cetyl alcohol is polypropoxylated cetyl alcohol].

13. A composition according to any of the preceding claims consisting essentially [substantially] of:

sorbitan tristearate or non-ionic emulsifying wax 0.5 to 5% w/v

glycerol monostearate	0.5 to 5% w/v
light liquid paraffin	1 to 20% w/v
white soft paraffin	1 to 10% w/v

iso propyl myristate	0.5 to 5% w/v
polar drug	0.1 to 20% w/v
disodium edetate	0.01 to 1% w/v
amphoteric surfactant	0.1 to 10% w/v
alkoxylated cetyl alcohol	0.1 to 10% w/v
triclosan	0.01 to 1% w/v
benzyl alcohol	0.01 to 1% w/v
purified water	to 100% of the emulsion

15. A method for topically delivering a pharmaceutical composition into a user's skin [treating a skin disease or condition], comprising:

(a) providing a polar drug selected from the group consisting of sodium cromoglycate and nedocromil sodium; and

(b) applying said polar drug to the skin of the user [an individual affected by the disease or condition] in or with a formulation comprising alkoxylated cetyl alcohol and an amphoteric surfactant.

17. A composition as in Claim 1 [that is useful] for [treatment of] treating a skin disease or skin condition selected from the group consisting of atopic dermatitis, contact sensitivity, psoriasis, drug sensitivity reactions, apthous ulcers, Behcet's syndrome, pemphigus, urticaria, urticaria pigmentosa, pyroderma gangrenosum, chronic skin

ulcers, ulcers associated with Crohn's disease, burns, insect stings/bites, herpetic infections, systemic sclerosis, morphoea, dermal nodular fibrosis or sunburn by applying said composition to the skin of an individual affected by the disease or condition.

21. A method as in Claim 15 for the treatment of a skin disease or skin condition selected from the group consisting of [in which the disease or condition is] atopic dermatitis [or eczema], contact sensitivity, psoriasis, drug sensitivity reactions, apthous ulcers, Behcet's syndrome, pemphigus, urticaria, urticaria pigmentosa, pyroderma gangrenosum, chronic skin ulcers, ulcers associated with Crohn's disease, burns, insect stings/bites, herpetic infections, systemic sclerosis, morphoea, dermal nodular fibrosis or sunburn.

22. A method according to Claim 21 [15] wherein the skin disease or condition is, has been or will be further treated by application of a corticosteroid.

Please add new Claim 30:

30. A method as in Claim 15 wherein said alkoxylated cetyl alcohol is polypropoxylated cetyl alcohol.

CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment in application Serial No. 09/701,140, filed November 21, 2000 of Brian Hawtin, entitled "FORMULATION" along with a transmittal cover letter are being deposited with the United States Postal Service as First Class mail, postage prepaid, in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D. C. 20231, on this 18th day of September, 2002.

Denise L. Siede
Secretary to Mark J. Burns
Attorney for Applicants

Date of Signature: Sept. 18, 2002